Amendments to the Specification:

Please replace paragraph [0030] with the following amended paragraph:

[0030] BPH involves overgrowth (hyperplasia) of cells in the prostate, resulting in enlargement of the prostate and leading to lower urinary tract symptoms and disease. The prostate gland contains secretory epithelial cells in a stroma of connective tissue and smooth muscle (see Barry, 2003, for a more detailed description of prostate anatomy), and BPH involves hyperplasia of the epithelial component. The secretory epithelial component in the normal prostate is remarkable in that the level of zinc in this tissue is very high compared to other normal tissues. A consequence of the high zinc levels is that, through a mechanism involving zinc inhibition of the enzyme m-aconitase, the generation of energy via the tricarboxylic acid (TCA) cycle and oxidative phosphorylation is substantially reduced in the secretory epithelium, making this tissue far more dependent than other organs and tissues upon glycolysis as an energy source. The zinc inhibition of m-aconitase, a key enzyme in the TCA cycle, results in at least a substantial reduction in, and perhaps a near complete blockade of, the TCA cycle in prostate epithelial cells. Another physiological result of the zinc-based inhibition of m-aconitase is the diversion of citrate from the TCA cycle, enabling the prostate to ~~secret~~ secrete large quantities of citrate, used by the sperm as an energy source, into the seminal fluid. See, generally, Costello, 1999; Costello *et al.*, 2000; Costello and Franklin, 2000.

Please replace paragraph [0031] with the following amended paragraph:

[0031] The present invention provides compositions and methods useful in the treatment of benign prostatic hyperplasia (BPH). In particular, the invention relates to the use of lonidamine (LND) for the treatment or prevention of BPH. Additionally, the invention relates to the use of lonidamine analogs for the treatment or prevention of BPH. To aid in understanding the invention, a brief discussion of BPH (also referred to as benign prostatic ~~hyperplasia~~ hypertrophy) and the properties of lonidamine and its bioactive analogs is provided below.

Please replace paragraph [0076] with the following amended paragraph:

[0076] Low dosing. Low dosing is contemplated for the treatment and ~~prophalaxis~~ prophylaxis of BPH. Exemplary low doses of lonidamine or a lonidamine analog include,

without limitation, doses in the range of 1-300 mg per day (total daily dosage), more often in the range of 5-300 mg/day, or sometimes in the range of 5-70 mg/day. Other exemplary low dose ranges include 1-25 mg/day, 20-45 mg/day, 40-65 mg/day, 40-70 mg/day, 50-100 mg/day, 50-200 mg/day, and 50-300 mg/day. In one embodiment, the low dose is 150 mg administered orally once per day; the Doridamina unit dose form can be used in this embodiment. In another embodiment, the low dose is 75 mg administered orally twice daily[,]; the Doridamina unit dose form can be used in this embodiment by splitting it into two equal parts.

Please replace paragraph [0087] with the following amended paragraph:

[0087] A preferred mode of delivery of lonidamine and lonidamine analogs to a patient is oral delivery. Preferred dosage forms for oral administration are pills, tablets, capsules, caplets, and the like, especially as formulated for sustained release. Other suitable forms for oral administration include troches, elixirs, suspensions, syrups, wafers, lozenges, and the like. Other modes of administration are also contemplated, including parenteral, inhalation spray, transdermal, rectal, ~~intraprostetic~~ intraprostatic injection (e.g., of lonidamine-containing microparticles) and other routes. lonidamine and lonidamine analogs may be formulated in suitable dosage unit formulations containing conventional non-toxic pharmaceutically acceptable carriers, adjuvants and vehicles appropriate for each route of administration. In one embodiment, the dosage form is the 150 mg unit dosage form marketed in Italy under the ~~tradename Doridamina~~ trade name DORIDAMINA.

Please replace paragraph [0091] with the following amended paragraph:

[0091] Glycolytic and Mitochondrial Function Inhibitors: Glycolytic inhibitors, such as 2-deoxy-D-glucose and compounds that inhibit glucose transport, mitochondrial function inhibitors, mitochondrial poisons, and hexokinase inhibitors such as 3-bromopyruvate and its analogs can also be used in combination with lonidamine or a lonidamine analog to treat BPH. Such inhibitors are known in the art, and include those described in PCT patent publications WO 01/82926 published 8 Nov. 2001; U.S. Pat. Nos. 6,670,330; 6,218,435; 5,824,665; 5,652,273; and 5,643,883; U.S. patent application publication Nos. 2003/0072814; 2002/0077300; and 2002/0035071; and U.S. patent application ~~Serial~~ No. 10/754,239 ~~10/_____ (filed 9 Jan. 2004; attorney docket number 54492-2000400) entitled "Treatment Of Cancer With 2-Deoxyglucose."~~

Such inhibitors can be administered in combination with lonidamine or lonidamine analogs for therapeutic benefit in the treatment of BPH.

Please replace paragraph [0098] with the following amended paragraph:

[0098] Surfactants suitable for use in the formulations of the invention include ionic and non-ionic surfactants or wetting agents such as ethoxylated castor oil, polyglycolyzed glycerides, acetylated monoglycerides, sorbitan fatty acid esters, poloxamers, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene derivatives ~~derivfatives~~, monoglycerides ~~nonoglycerides~~ or ethoxylated derivatives thereof, sodium lauryl sulfate, lecithins, alcohols, and phospholipids.

Please replace paragraph [0109] with the following amended paragraph:

[0109] The sustained release formulations of the invention also contain in some embodiments one or more pharmaceutical excipients intimately mixed with the ~~ranolazine (Lonidamine)~~ lonidamine and the pH-dependent binder, such as pH-independent binders or film-forming agent, starch, gelatin, sugars, carboxymethylcellulose, and the like, as well as other useful pharmaceutical diluents such as lactose, mannitol, dry starch, microcrystalline cellulose, and the like, and surface active agents such as polyoxyethylene sorbitan esters, sorbitan esters, and the like; and coloring agents and flavoring agents. Lubricants such as talc and magnesium stearate and tableting aids are also present.

Please replace paragraph [0121] with the following amended paragraph:

[0121] Immunoblotting: Immunoblotting was carried out as described in Example 2. To detect the expression of caspase 3, the membrane was blocked with TBST containing 5% non-fat milk for 1 h at room temperature, and caspase 3 protein was detected by incubation with caspase 3 antibody ~~for~~ overnight at 4^0C and with the alkaline phosphatase-conjugated secondary antibody for 1 h. The specific protein was detected using colorimetric substrate, and the intensity of each protein was quantified using an NIH image system.